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The Food Safety People

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ASSOCIATION

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Dockets Management Branch (HFA-305)
Office of Policy
Food and Drug Administration
5630 Fishers Lane Room 1061
Rockville, MD 20852

Re: Docket No. 1998N-0583 Exports: Notification and Recordkeeping Requirements; Advance Notice of Proposed Rulemaking (ANPR) 69 Federal Register 30842, June 1, 2004.

Dear Sir or Madam:

The National Food Processors Association (NFPA) appreciates this opportunity to provide comments on the above referenced advance notice of proposed rulemaking (ANPR) regarding records that are kept to demonstrate that an exported product does not conflict with the laws of the foreign country for which it is intended for export. **NFPA recommends revising 21 CFR § 1.101 and believes that the assertions in the petition referenced in the ANPR are correct. FDA lacks the authority to require food exporters to maintain particular records to demonstrate compliance with the laws of the country for which a food product is intended for export or to require inspection of those records.**

NFPA is the voice of the $500 billion food processing industry on scientific and public policy issues involving food safety, food security, nutrition, technical and regulatory matters and consumer affairs. NFPA's three scientific centers, its scientists, and professional staff represent food industry interests on government and regulatory affairs and provide research, technical services, education, communications and crisis management support for the Association's U.S. and international members. NFPA members produce processed and packaged fruit, vegetable, and grain products, meat, poultry, and seafood products, snacks, drinks and juices or provide supplies and services to food manufacturers. NFPA members export products globally and are affected by this rule.

As A General Matter, FDA Lacks the Legal Authority to Require Inspection of Records Relating to Exported Food Products

NFPA believes that the challenges raised by the petition continue to be valid as they relate to this particular rulemaking. The Bioterrorism Act of 2002 gives

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the Secretary records inspection authority with respect to foods when there is "a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans and animals." Records access authority under the Bioterrorism Act does not extend across the board to records related to an exported food's compliance with foreign country laws or to records retention pertaining to food exports.

Although the ANPR makes reference to the FDA Export Reform and Enhancement Act, that legislation was intended by Congress to facilitate the export of nonconforming products manufactured in the United States and, with respect to foods, is specifically limited to food additives, color additives and dietary supplements. It does not provide authority to inspect records relating to the export of all foods for the purpose of demonstrating compliance with foreign laws. Again, NFPA asserts that the position put forward in the petition continues to be valid.

FDA Lacks the Legal Authority to Require Food Exporters to Maintain Particular Records to Demonstrate Compliance with the Laws of the Country for Which the Exported Food Is Intended

The Federal Food, Drug, and Cosmetic Act (FFDCA) places the burden of demonstrating noncompliance with the law of the importing country on FDA. It is the responsibility of the exporter to comply with the laws of the importing country, but it is not the exporter's responsibility to demonstrate to FDA it's compliance with a foreign country's law or to do so by maintaining any particular records.

Unless specific agreement has been reached with an importing country (such as with the EC for products of animal origin), FDA has historically denied any obligation to ensure compliance with the regulations of other national governments or to attest to that compliance through export certification. The FDA certificate of free sale for FDA regulated food products attests to the fact that the product can be freely sold within the U.S. of particular relevance, is the language which states that, "It is the responsibility of the manufacturer and/or distributor to market a safe and properly labeled product...."

In cases where specific product attestations are requested by importing countries, FDA has often entered into agreements with those countries to defer the certification to agencies, such as the USDA Agricultural Marketing Service (AMS) that certifies exported dairy products to comply with EC regulations. NFPA agrees with the petitioner that the specific language within Section 801(e) of the FFDCA, and subsequent actions by FDA related to the certification and verification of products for export, demonstrates that FDA has not historically assumed the burden of demonstrating compliance of exports with foreign law.

Moreover, FDA should not be concerned about compliance with the regulations of other nations. That enforcement burden is the sovereign responsibility of the importing

country. Consequently, NFPA does not believe exporters should have to show FDA these records unless requesting specific attestations from FDA as a condition of importation or unless a domestic food safety problem is linked to an exported food product.

The Regulation Should Not Be Applicable to Food Products.

In June 1999, NFPA submitted comments stating that the recordkeeping requirements as then proposed by FDA were "entirely inappropriate" for food product exports. At that time, NFPA pointed out that:

- The requirements did not accurately reflect the intent of the statutory provisions under the FDA Export Reform and Enhancement Act of 1996 in that Congress intended to "substantially reduce the requirements" for exporting products that were unapproved by FDA and thus facilitate their export to destinations where they were compliant. The Act was not intended to apply to food generally but only to additives, colors and dietary supplements.
- The documentation requirements proposed to verify importing country requirements were unnecessary and excessively burdensome and extended beyond FDA authority.
- The proposal underestimated the recordkeeping burden on the food industry to comply.

NFPA reiterates our earlier strong opposition to this rulemaking, again citing an unnecessary and unjustifiable burden on the food industry and strongly urges amendment to §1.101.

FDA asks what are the advantages and disadvantages of a certification in some food export situations. NFPA maintains that providing certification to demonstrate compliance with foreign country laws, places an unnecessary recordkeeping burden on the food industry and on the Agency. Notarized statements would be especially difficult to obtain. U.S. manufacturers export almost $30 billion in processed food products annually. As is appropriate, these products are often specifically formulated and packaged to meet the importing country requirements that may differ from those of the U.S. There is no evidence to suggest that U.S. food companies are exporting products without due regard for compliance with the regulations of other nations. Nor is there any legal or reasonable justification for FDA to assume enforcement responsibility for those nations' regulations. FDA has neither the mandate nor the resources for such a task.

Furthermore, implementation of 1.101 (b) invites importing nations to shift the burden of ensuring regulatory compliance to FDA by requesting specific attestations or certifications that FDA has historically resisted, and NFPA again stresses that the Agency is without either the authority or resources for such a function.

If, despite questionable legal authority, FDA goes forward to implement 1.101(b), limiting the scope of the regulation so that it applies only to those food products that do not conform to FDA requirements for reasons related to safety (e.g., for reasons other than labeling, packaging or other technical or marketing (standards of identity) requirements) would substantially diminish the recordkeeping burden on the food industry. In such a case, a flexible approach to determine compliance with foreign regulations should prevail; certificates should not be required. A food company needs the discretion to retain those records that may be deemed sufficient and appropriate to both the product and the export market. Importing countries routinely ascertain compliance for new products through registration and approval procedures in which FDA is not engaged. Consequently, in most cases a specific certification would be unnecessary for a food manufacturer to prove compliance with foreign country laws should the need arise.

Summary

NFPA strongly believes that 1.101 should be revised and that food products should be excluded from the scope of this regulation for the following reasons:

- There is no legal authority for FDA to inspect records relating to food exports generally or to mandate that companies maintain particular records to demonstrate compliance with the regulations of foreign countries.
- The certification approach in the final rules and suggested within the ANPR would present a significant recordkeeping burden, without having any impact on the safety of the domestic food supply.
- FDA's suggestion of requesting "letters" from other national authorities interferes with the jurisdictional authority of the importing country without justification; countries would have no reason to respond to such a request especially if the import competes with domestic industries.
- Historically, FDA has resisted export certification to verify compliance with importing country requirements and has taken the position that this responsibility rests with the exporter.
- FDA should not be overburdened by verifying requirements that are the sovereign responsibility of other governments.

FDA asks for a simple record, as an alternative to certification, that "permits enforcement action in the United States," but, as discussed earlier, FDA does not have the authority to inspect such a record or to mandate its retention.

NFPA urges FDA to revise its regulations pertaining to export notification and recordkeeping as they relate to foods.

Thank you for consideration of these comments.

Sincerely,

John Cady